5.0 510(k) Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the TTS Esophageal Stent device is provided below.

Device Common Name: Esophageal Prosthesis

Device Proprietary Name: Esophageal TTS Stent

Submitter:
Taewoong Medical Co., Ltd.
1-5, Gomak-ri, Wolgot-myeon, Gimpo-si, Gyeonggi-do, Korea 415871
TEL: +82-31-996-0641
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Contact:
Stephen P. Rhodes
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Biologics Consulting Group, Inc.
Phone: (301) 579-3700
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Classification Regulation: 21 CFR 878.3610

Panel: General & Plastic Surgery Devices

Product Code: ESW

Predicate Devices:
K080782 - Taewoong Niti-S Esophageal Stent
K073667 - Taewoong Niti-S Biliary Stent

Indication for Use:
For use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.

Device Description:
The Esophageal TTS Stent consists of an implantable metallic stent and a flexible introducer system. The stent is a flexible, expandable tubular device made of Nitinol wire and covered with silicone. This device also includes a disposable introducer. Upon deployment, the stent imparts an outward radial force on the luminal surface esophagus to establish patency.

Comparison to the Predicates
The Esophageal TTS Stent is substantially equivalent to the Niti-S Esophageal Stent cleared in K080782 with respect to the materials, design, and range of available sizes.

The introducer used to deliver the Esophageal TTS Stent is the same as the introducer cleared for use with the Niti-S Biliary Stent (K073667), except that the diameter is slightly larger to match the diameter of the esophageal stent. The materials, length and manufacturing are the same as previously cleared introducer.

Performance Data:
Per FDA "*Guidance for Industry – Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses*," the following tests were conducted:

- Deployment Testing
- Expansion Force Testing
- Compression Force Testing
- Dimensional Testing
- Tensile Strength Testing

The following testing was also conducted:

- Packaging Adhesive Testing
- MR Compatibility

Summary of Substantial Equivalence:
Based on the indications for use, technological characteristics and performance test results, the Esophageal TTS Stent is substantially equivalent to the predicate Niti-S Esophageal Stent and Niti-S Biliary Stent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Taewoong Medical Co., Ltd.
% Mr. Stephen P. Rhodes
Senior Consultant
Biologics Consulting Group, Inc.
400 N. Washington St. Suite 100
ALEXANDRIA VA 22314

FEB 14 2012

Re: K113551
Trade/Device Name: Esophageal TTS Stent
Regulation Number: 21 CFR§ 878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: ESW
Dated: December 1, 2011
Received: December 1, 2011

Dear Mr. Rhodes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4.0 Indications for Use Statement

510(k) Number (if known): K113551

Device Name: Esophageal TTS Stent

Indications For Use:

For use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.

Prescription Use __X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113551

Page 1 of __1__